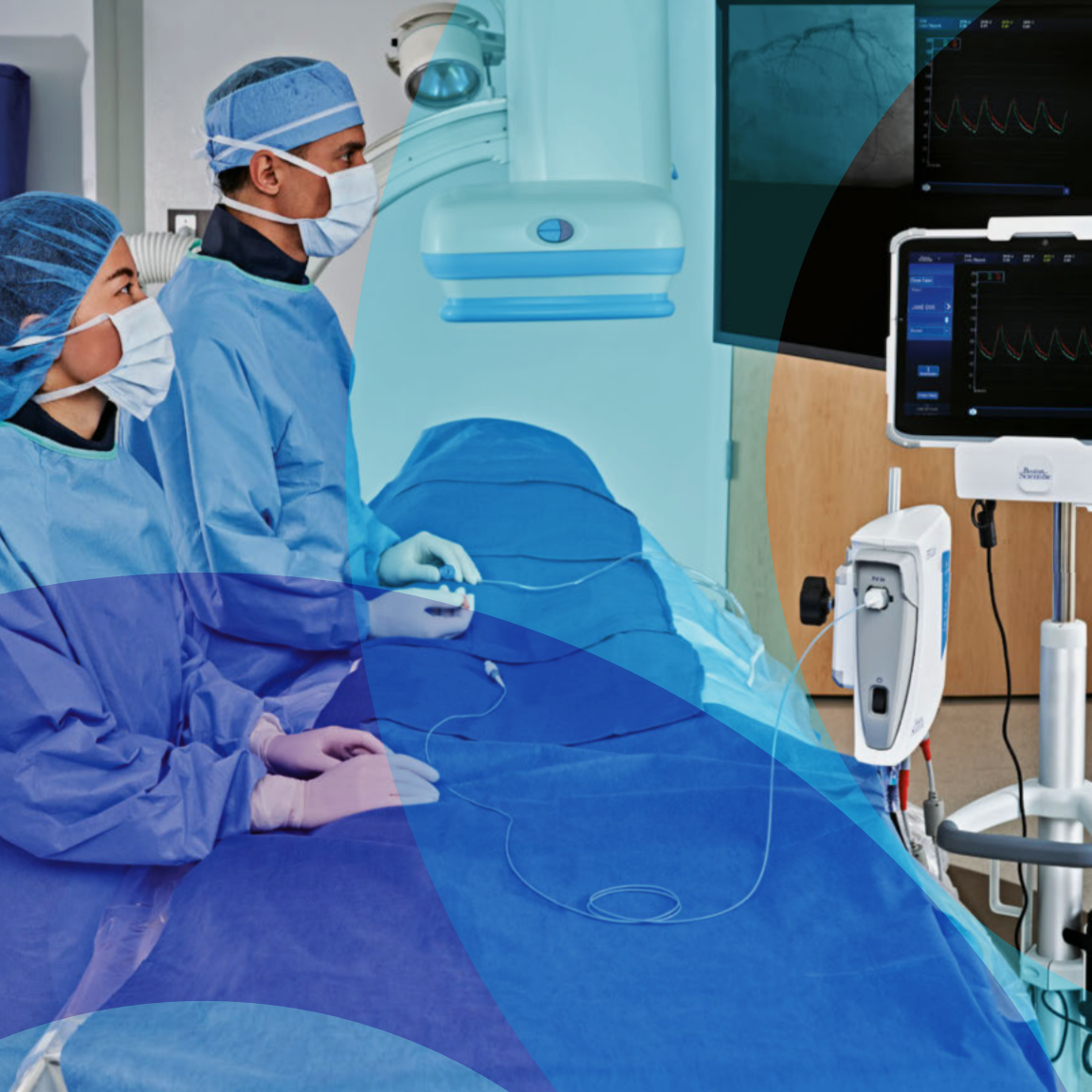
Boston Scientific
Advancing science for life™

AVVIGO™
Guidance System

A New Era in Every Lab

The AVVIGO Guidance System is the only system that offers the game-changing performance of the COMET™ II Pressure Guidewire with your choice of physiology modality in a flexible, tablet-based platform.



Built for performance. Fit for you.

An easy-to-use, tablet-based platform that seamlessly integrates with the FFR Link and our workhorse COMET™ II Pressure Guidewire to provide a suite of resting and hyperemic physiology measurements.

AVVIGO Tablet

- Always ready for your patient, this tablet has an easy-to-use touch screen that starts up in an instant
- Flexible set-up configurations for every lab
- Suite of physiology indices: FFR, DFR™, and Pd/Pa
- SmartMinimum™ automatically removes artifacts to help you quickly identify the true FFR value

FFR Link

- Simple bedside mount
- Compatible with your hemodynamic system
- Seamless Bluetooth™ connection with AVVIGO™ Guidance System

COMET™ II Pressure Guidewire:
Total Confidence in Your Treatment Decision.

Deliverability
- Shapeable and atraumatic Asahi tip
- Precision cut body for 1:1 torque

Accuracy
- Optical technology for exceptional drift performance and reliable signal connection

Usability
- Optimized rail support for device delivery
- Free-spinning, quick-release handle
- One wire for the entire procedure

ASAHI TECHNOLOGY

Diastolic hyperemia-Free Ratio™ (DFR) and SmartMinimum™ (smFFR)

- DFR calculates a diastolic portion of the cardiac cycle at rest. DFR uses a cutoff of 0.89 and is numerically identical to iFR. The DFR window uses two criteria: Pd < mean Pa and down-sloping Pa. No ECG signal is required.
- smFFR automatically excludes certain artifacts (e.g., flushing, opening AO stopcock or hemostasis valve, pulling out guidewire during recording) to latch to the true FFR value.

DFR

smFFR

Ordering Information

Description	GTIN	Ref/Catalog Number
AVVIGO™ Guidance System	08714729996538	H749 **009761** 0
FFR Link	08714729890010	H749 **555100** 0
COMET II™ Pressure Guidewire	08714729960140	H749 **3935911** 0

FFR LINK: INTENDED USE/INDICATIONS FOR USE The FFR Link is intended to condition physiological signals from measuring devices (BSC Pressure Guidewire or an external pressure transducer), transmit and receive via radiofrequency, and recondition the signals so they can be displayed on and/or recorded in a receiving device (iLab™ POLARIS Multi-Modality Guidance System or other monitoring device). The physiological signals can also be distributed by cable. **CONTRAINDICATIONS** The FFR link has no patient alarm functions and should not be used for cardiac monitoring. **WARNINGS AND PRECAUTIONS** Use only a Boston Scientific Comet™ Pressure Guidewire or other Boston Scientific pressure guidewire with the FFR Link. Use of pressure guidewires from other manufacturers will provide inaccurate pressure readings. The FFR link maintains a floating double-insulated patient isolation connection. This connection is intended for defibrillator-proof direct cardiac application (type CF), and includes circuitry to limit the patient leakage current to the levels specified in UL2601-1, EN60601-1, and JIS-T-060101.

COMET II Pressure Guidewire: INTENDED USE/INDICATIONS FOR USE The Comet II Pressure Guidewire measures blood pressure gradient across coronary and peripheral lesions during endovascular procedures. FFR (Fractional Flow Reserve) pressure guidewire may also be used as a coronary or peripheral guidewire for interventional treatments. The Comet II Pressure Guidewire is indicated to direct a catheter through a blood vessel and to measure physiological parameters in the coronary and peripheral blood vessels. **CONTRAINDICATIONS** The Comet II Pressure Guidewire is contraindicated for use in the cerebral vasculature. **WARNINGS** • Resulting pressure guidewire fractures/separations might require additional percutaneous intervention or surgery. • Use extreme caution and careful judgment in patients for whom anticoagulation is not indicated. • Severe reaction may occur in response to contrast agents that cannot be adequately premedicated. **PRECAUTIONS** Maintain diligent control of the distal tip at all times during an intervention to avoid vessel dissections and perforations. Wire damage may occur when the pressure guidewire is manipulated in a sharp bend, such as that caused by incomplete coaxial alignment of the delivery catheter and ostium, creating a sharp bend of the pressure guidewire between the delivery catheter and the vessel wall. Sharp bends are more likely to occur when using a less supportive delivery catheter, such as a diagnostic catheter. When crossing a stent, exercise care to avoid entanglement between the pressure guidewire and the stent. Avoid abrasion of the pressure guidewire coating. - To avoid damage to the hydrophilic coating, do not withdraw or manipulate the pressure guidewire in a metal cannula or sharp object. - Excessive tightening of the torque device onto the pressure guidewire may result in abrasion of the coating on the pressure guidewire. Use only the optical cable provided to connect the pressure guidewire to FFR Link. Use of a different optical cable will produce inaccurate pressure readings. The accuracy of the diagnostic information is affected by, but not limited to: - Failure to achieve maximum coronary and myocardial hyperemia if using FFR (Fractional Flow Reserve) modality. - Interventional devices, such as balloon catheters, which are positioned so as to affect the blood flow or guidewires that stretch the vessel. - Pressure wire positioning relative to the lesion. - Microvascular resistance. Carefully check and match therapeutic device compatibility to the pressure guidewire prior to use. Do not use the pressure guidewire in conjunction with atherectomy catheters. **ADVERSE EVENTS** Potential adverse events which may result from the use of the device include but are not limited to: • Abrupt closure • Allergic reaction • Embolism • Exposure to biohazardous material • Infection • Prolonged procedure • Restenosis (reocclusion) • Spasm • Stroke/cerebral vascular accident (CVA)/transient ischemic attack (TIA) • Vascular thrombus • Vessel trauma (dissection, perforation, rupture or injury) In addition, when used for interventional procedures: • Angina or unstable angina • Arrhythmias • Cardiac tamponade/pericardial effusion • Contrast induced renal insufficiency or renal failure • Death • Myocardial infarction or ischemia Some of the above potential adverse events may require additional surgical intervention. **Caution:** Federal law (USA) restricts this device to sale by or on the order of a physician. Rx only. Prior to use, please see the complete "Instructions for Use" for more information on Indications, Contraindications, Warnings, Precautions, Adverse Events, and Operator's Instructions. 92499586A

AVVIGO Guidance System: INTENDED USE / INDICATIONS FOR USE FFR and DFR are intended for use in catheterization and related cardiovascular specialty laboratories to compute, and display various physiological parameters based on the output from one or more electrodes, transducers, or measuring devices. FFR and DFR are indicated to provide hemodynamic information for use in the diagnosis and treatment of patients that undergo measurement of physiological parameters. **CONTRAINDICATIONS** The FFR / DFR modalities of the System has no patient alarm functions and should not be used for cardiac monitoring. **WARNINGS** • The System can only be used with Boston Scientific specified accessories and cables. The use of accessories and cables other than the items provided by Boston Scientific may result in increased emission or decreased immunity of the System. For questions regarding this matter, please contact Boston Scientific for technical assistance. • The System is intended for use by healthcare professionals only. This equipment / system may cause radio interference or may disrupt the operation of nearby equipment. It may be necessary to take mitigation measures, such as reorienting or relocating the AVVIGO System or shielding the location • Inappropriate use of the System may lead to patient illness or injury. Please read this User Guide and the DFUs for the FFR link and pressure guidewires carefully and completely before attempting to use the System. • Inappropriate use of the System may lead to misinterpretation of patient data and subsequent misdiagnosis / mistreatment, potentially leading to injury. **ADVERSE EVENTS** None known **CAUTION** Federal law (USA) restricts this device to sale by or on the order of a physician. Rx only. Prior to use, please see the complete "User's Manual" for more information on Indications, Contraindications, Warnings, Precautions, Adverse Events, and Operator's Instructions. 92580420 A

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To order product or for more information contact customer service at 1.888.272.1001.

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